Nevada Medicaid
Pharmacy & Therapeutics Committee

Location of Meeting
401 South Carson Street, Room 2135, Carson City, NV

Teleconference
555 E. Washington, Room 4406 Las Vegas, NV

MEETING MINUTES OF
May 27, 2004
1:00 p.m.

Committee Members Carson City:
Steven Phillips, MD, Chairman
Judy Britt, PharmD
Carl Heard, MD
Thomas Wiser, PharmD

Committee Members in Las Vegas:
Diana Bond, RPh
Linda Flynn, RPh
Alan Greenberg, MD
Robert Horne, MD

Absent: Larry Pinson, PharmD
Susan Pintar, MD

Others Present:
Carson City:
Darrell Faircloth AGO,Coleen Lawrence DHFCP, Nancy Davis DHCFP, Jeff Monaghan First Health Services Corporation, Dawn Daly First Health Services Corporation, Jamie Wyels First Health Services Corporation, Bert Jones GSK, Slater Sparks Bertel, Liz MacMenamin RAN, Eric Pekzan Schwarz, Kimmy Naik Reliant, Lawrence Stack Reliant, Alena Jandourek Ortho-Mcneil, Keven Jensen MD Sierra View Medical Center, Jennifer Brown Speracor, Tracy Davies Lilly, Jonathan Raap Aventis, Jake Mater Aventis, Rob Kiddos Pfizer, Steve Schaerrer Astra Zeneca, Ellen McCormick Astra Zeneca, Stuart Stoloff MD, Doug Ethel GSK, Henry Hough 60 Plus Association, Tucker Thole MD, Mark Pezdutz GSK, Kate Ryan Astra Zenceca, Maria Papyoti Astra Zeneca, Barbara Jo Wilson Bayer, David Armstrong Schering Plough, Derek Naten Bayer

Las Vegas:
Paul Patel Ortho-McNeil, Don Roberts UMC, Ron Taylor Ortho-McNeil, Dick Krospel Abbott, Coleen Fong BMS, Jennifer Lauper BMS, Paul Pereira Tap, Emerald Foster Nevada Care, Dee Dee VanWorner Pfizer, Bos Mendes Pfizer, Catherine Harris Pfizer, Sondra Rohac Bayer, Jeanette Belz Astra Zeneca, Roland Baldwin Wyeth, Kirk Huffner Nevada, Harvey Roseberg Resource Pharmacy, Sedrick Spencer Roche.

I. Call to Order and Roll Call

Chairman Steven Phillips called the meeting to order at 1pm. Committee members present in Las Vegas: Diana Bond RPh, Linda Flynn RPh, Alan Greenberg MD, and Robert Horne MD. Members present in Carson City: Steven Phillips MD, Judy Britt PharmD, Carl Heard MD, and Thomas Wiser PharmD.

Dr. Phillips stated they would not review the calcium channel blocker combinations as a group, since each entity would be or has been reviewed as a single entity. This approach would be applied to all combination agents in the future. He also stated that only the statin class of drugs would be included in the Lipotropic review scheduled for today's meeting.

II. Approval of Minutes of April 22, 2004 Meeting

Dr. Phillips clarified the section of the minutes that stated all members were present. He stated this actually was referring to the members physically present.

Page 2, item 3 change “origin” to “original”

Motion to Accept: Dr. Wiser
Seconded: Dr. Britt
Ayes: Unanimous

Motion Carried

III. Calcium Channel Blockers and Combinations

Public Comment:
Dawn Daly, FHSC, stated that the written comments received had been provided to the committee members.

Las Vegas:
Bob Mendes, MD, Pfizer-Discussion of Norvasc. Attachment

Carson City:
Kate Ryan, Astra- Zeneca -Gave an overview of Plendil
Kimmy Naik, Reliant-Discussed Dynacirc. Attachment
Dr. Britt asked who sponsored the studies. Ms. Naik stated to her knowledge these studies were not funded by drug companies.
Jamie Wyels, FHSC, gave an overview of the dihydropyridine calcium channel blockers.
Dr. Heard asked about the difference in the timed release agents as compared to Norvasc, which has a longer half-life. He also asked if nursing home patients would be carved out of the PDL process. Dr. Phillips stated they are looking for therapeutic alternatives and some agents will have different dosing schedules. Dr. Monaghan stated that nursing homes will not be carved out of the PDL process. He also stated that an agent with a longer half-life will not necessarily have a longer duration of action.

Dr. Greenberg commented nimodipine is only indicated for subarachnoid hemorrhage, is usually started in the hospital, and has a short duration of therapy, usually about 3 weeks. He also commented that the immediate release preparations are not recommended due to their wide fluctuations in blood pressures and should be excluded from the class.

Jamie Wyles, FHSC, gave an overview of non-dihydropyridine calcium channel blockers

Dr. Britt commented that the short acting agents should be excluded and there is equivalency with the other dihydropyridines. She further stated that there is overall equivalency, although there are a few exceptions where Norvasc would be indicated. Dr. Wiser agreed.

Motion: Dr. Heard made the motion that in the treatment of congestive heart failure and hypertension, with exclusion of short acting dihydropyridines and the caveat nimodipine be indicated for subarachnoid hemorrhage the dihydropyridines are therapeutic alternatives.
Seconded: Dr. Wiser

No discussion

Vote: Ayes: Unanimous

Motion carried.

Motion: Dr. Wiser motioned for the non- dihydropyridine calcium channel blockers diltiazem and verapamil to be considered therapeutic alternatives, and Bepredil be considered for non- preferred status
Seconded: Dr. Britt
Amendment by Tom Wiser for the non- dihydropyridine calcium channel blockers, diltiazem and verapamil, be considered therapeutic alternatives for hypertension & angina.
Seconded: Dr. Britt
Vote: Ayes: Unanimous
Motion carried.

IV. Inhaled and Nebulized Corticosteroids

Public Comment:
Dawn Daly, FHSC, stated written comments have been provided to the committee members.
Maria Papayoti, Astra- Zeneca-Gave an overview of Pulmicort.
Stuart Stoloff, family physician-Gave an overview of Flovent.
Doug Ethel, GSK was here with Dr. Stoloff
Dr. Britt asked about dosage of Advair for COPD. Dr. Stoloff responded that the 250/50 should be utilized; there were no studies done utilizing the 100/50. Dr. Heard asked if Dr. Stoloff had an affiliation with GSK. Dr. Stoloff stated no and is not receiving any remunerations. Dr. Heard asked Dr.Stoloff to rank the drugs. Dr. Stoloff ranked fluticasone, budesonide for monotherapy and uses Advair for combination. Dr. Wiser asked about bioavailability, if there was a difference, and what is the implication. Dr. Stoloff stated the drug you would be most concerned about in this class is beclomethasone because it disperses into monopropionate and dipropionate molecules. He also stated the systemic absorption at lower doses of 400mcg or less the question would be how effective these products would be. If you had to rank these agents it would be fluticasone, then budesonide at these doses. Dr. Greenberg asked about the efficacy rotadisk versus the nebulizer. Doug Ethel responded there are no head to head studies.

Jamie Wyles, FHSC, gave an overview of the class.
Tom Wiser stated he was very concerned about the systemic absorption of these drugs. Dr. Phillips stated Dr. Stoloff talked about mono and dipropionate molecules and there is a difference in the metabolism of the agent. Diana Bond asked why are we dealing with the combinations. Jamie Wyles stated he wanted to acknowledge the combinations but was actually focusing on fluticasone. Dr. Phillips stated we are just looking at the corticosteroid component, since the beta agonists have already been reviewed.

Judy Britt stated there is more literature regarding beclomethasone and flunisolide and the effect on growth studies.

Motion: Diana Bond motioned that for the adult population the five products are therapeutic alternatives and have fluticasone and budesonide for ages 4 and up and budesonide for ages 12 months and up.
Seconded: Dr. Britt

Dr. Horne stated he would have trouble supporting the motion and wanted to amend the motion to include fluticasone and exclude beclomethasone. Dr. Heard asked Diana to make a friendly amendment to take beclomethasone off the preferred and make fluticasone and budesonide on the PDL. Diana Bond stated she would make the motion with the exception of beclomethasone. All other drugs in this class are therapeutic alternatives in the adult population and the pediatric population will have fluticasone and budesonide for ages 4 and up and budesonide for ages 12 months and up.

Motion: Diana Bond made a friendly amendment that all the drugs with the exception of beclomethasone are therapeutic alternatives in the adult population and the pediatric population have fluticasone and budesonide for ages 4 and up and budesonide for ages 12 months and up.
Seconded: Dr. Britt

Vote: Ayes: Unanimous

Motion carried.

V. Nasal Steroids

Public Comment:

Dawn Daly, FHSC, stated written comments have been provided to the committee members.

David Armstrong, Schering Plough, gave an overview of Nasonex (mometasone). Dr. Heard asked about the bioavailability. He responded that the bioavailability is 97% in the nasal passages. Diana Bond asked for a clarification on the indication for age. He stated mometasone can be used for ages 2 years and older.

Maria Papayoti, Astra Zeneca, gave an overview of budesonide.

Tucker Thole, MD, Sparks, NV, recommended Flonase be on the PDL. Dr. Phillips asked if he represented anyone. He stated no and his specialty was family and sports medicine. Dr. Britt asked if in his practice he saw any patient variability regarding preference and did he tend to use samples. He responded he does not use samples for allergic rhinitis and simply prescribes Flonase. He stated there is variability among patients in his practice, if they do not like one agent then he prescribes an alternative intranasal spray.

Jonathan Rapp, Aventis, gave an overview of the class and Nasacort AQ. Dr. Wiser asked about the wide difference in bioavailability and how does he comparatively view this issue. He responded that based on the available and accepted pharmacological measuring tools, nasal bioavailability is not a predictor of safety.

Coleen Lawrence stated that there has been a lot of reference to the pediatric population. She informed the committee most of the pediatric population is under managed care and the pediatric population is a very small portion of the patients affected by the PDL.

Jamie Wyles, FHSC, gave a comparative overview of the class.

Dr. Heard asked about the diluent and if the label does not state AQ can it be assumed that it is alcohol-based. Dr. Monaghan responded he did not have that information, but it would be safe to assume that the non-AQ formulations contain some form of alcohol.

Motion: Dr. Wiser moved that all drugs in this class be therapeutic alternatives.
Seconded: Linda Flynn
Diana Bond made a friendly amendment that when First Health Services comes back with a recommendation to include a drug that can be used down to age 2.
Dr. Wiser accepted the friendly amendment and Linda Flynn seconded.
Vote: Ayes: Unanimous.

Motion carried

Recess

VI. Quinolones: Second Generation

Public Comment:

Barbara Jo Wilson, Bayer, gave an overview of Cipro XR. Judy Britt asked if she had literature comparing once a day dosing versus twice a day dosing. . Ms. Wilson stated there is a study that will be published soon. Dr. Heard asked about resistance. Ms. Wilson responded the large studies are still showing ciprofloxacin has good clinical outcomes when treating E. coli cystitis.

Dr. Monaghan, FHSC, gave a comparative overview of the class.

Ms. Bond asked if the ophthalmic will be included. Dr. Monaghan responded these will not be addressed. Dr. Wiser asked for clarification on indications. Dr. Monaghan stated that the agents are therapeutic alternatives for the vast majority of clinical uses, however differences do exist based on kinetic profiles and local culture and sensitivity profiles.

Dr. Greenberg commented on the resistance issue and stated it is a class effect from overuse of quinolone antibiotics. Lomefloxacin has poor pneumococcal activity. Ciprofloxacin has advantages in this class with gram negative activity. There is usage of ciprofloxacin in pediatric patients with cystic fibrosis. Ciprofloxacin has a broad spectrum of activity and it should be on the PDL.

Motion: Diana Bond motioned that ciproflxoacin, lomefloxain and ofloxacin be considered therapeutic alternatives.
Seconded: Dr. Greenberg

Vote: Ayes: Unanimous

Motion carried.

VII. Quinolones: Third Generation

Public Comment:
Donald Roberts, MD, UMC, identified himself as a resident preceptor and patient advocate and did not represent any manufacturer. Dr. Roberts voiced his opposition to gatifloxacin due to its adverse drug reaction profile, particularly to the increased incidence of C. difficile he had observed at UMC. Dr. Greenberg stated that there are other drugs such as clindamycin, Unasyn and Zosyn that are associated with C. difficile, and asked Dr. Roberts if he had UMC data on these drugs regarding utilization and incidence of C. difficile. Dr. Roberts stated he has started chart reviews from 2003 and gatifloxacin was associated with the documented discharge diagnosis of C. difficile in the majority of charts he reviewed. Beyond that, he stated he had not broken down the data. Dr. Greenberg stated that the study that had been referred to earlier was from a VA chronic care facility, not an acute care hospital, .and the increased incidence of C. difficile was limited to patients on gatifloxacin greater than 10 days. Dr. Britt asked about his statement that of the adverse events observed, 70% from gatifloxacin, which had only a 7% market share. She also asked for the percentage of adverse events related to glucose homeostasis. Dr. Roberts responded glucose homeostasis accounted for the vast majority of the adverse drug reactions. Dr. Wiser asked for the number of C. difficile infections related to gatifloxacin. Dr. Roberts stated 66% were associated with Tequin in 2003. Dr. Greenberg asked what type of glucose homeostasis problems were being observed, hypoglycemia or hyperglycemia ? Dr. Roberts responded most instances of hyperglycemia appear to be related to long term therapy versus hypoglycemia in shorter term therapy. He also stated this was predominantly in the older population but has had this occur in a young patient. Dr. Phillips asked if this is intravenous or oral use. Dr. Roberts stated oral use is associated with it, but all of his

cases have been related to intravenous use. He also stated that he was not aware of the incidence of outpatient-related problems at UMC.
P.Patel & Alena Jandourek, Ortho, gave an overview of Levaquin. Dr. Wiser asked about the incidence of C. difficile with their product. Dr. Jandourek responded the data shows the incidence is fairly low. Dr. Greenberg asked if there were any studies comparing levofloxacin against other third generation quinolones with regard to of C. difficile or glucose homeostasis. She stated there are no direct comparison studies.

Barbara Jo Wilson, Bayer-Gave an overview of Avelox. Judy Britt asked if she had the statistics of the QT prolongation with the different products. She only had statistics for her product. Dr. Heard asked why there is no dosage adjustment in renal or hepatic disease. She stated no adjustment was necessary due to the dual metabolic elimination pathway, i.e. hepatic and renal.

Dr. Monaghan, FHSC, gave a comparative overview of the class.

Dr. Wiser asked why the market share is so high for Levaquin when gatifloxacin is the workhorse for the large hospitals in Nevada. Dr. Monaghan responded the market share reports represent outpatient prescriptions. Dr. Heard stated that he wanted to address the C. difficile issue. Dr. Britt suggested a literature search regarding the issues. Dr. Horne would like to look at the glucose problem. Diana Bond asked for confirmation that gatifloxacin has in fact been pulled from the market in Europe and Japan. Dr. Greenberg stated the C. difficile problem addressed brought to light at the Atlanta VA chronic care facility was related to use beyond 10-11 days. This was just an observation, not a study. Glucose homeostasis reports are anecdotal, with more reports appearing to be related to gatifloxacin. Dr. Phillips stated that in chronic care 60-70% of residents are carriers of C. difficile. Dr. Phillips requested further data for the July meeting when the PDL is chosen.

Motion: Dr. Greenberg- The drugs in this class should be considered therapeutic alternatives. Current information regarding glucose homeostasis and C. difficile should be presented at the July meeting.
Seconded: Dr. Heard

Vote: Ayes: Unanimous

Motion carried.

VIII. Lipotropics

Public Comment:

Colleen Fong, BMS,gave an overview of Pravachol
Bob Mendes, Pfizer, gave an overview of Lipitor-Attachment
Dr. Greenberg asked if there is any evidence that atorvastatin does anything in addition in LDL lowering that would make it stand out in this class. Dr. Mendes stated that remains to be determined.
Henry Hough, 60 Plus Association-Attachment
Kate Ryan, Astra-Zeneca, gave an overview of Crestor. Attachment
Dr.Wiser asked if Crestor is it the most potent drug in this class. Ms. Ryan stated it was the most efficacious.

Dr. Heard excused himself.

Kimmy Naik, Novartis, gave an overview of Lescol & Lescol XL-Attachment

Dr. Britt asked if the drug was lipophilic or hydrophilic. Ms. Naik stated it was equally lipophilic and hydrophilic.

Dawn Daly, FHSC, stated written comments had been provided to the committee.

Dr. Monaghan, FHSC, gave a comparative overview of the class.

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Motion: Dr. Wiser- The statin agents presented be considered therapeutic alternatives.
Seconded: Dr. Horne
Diana Bond made a friendly amendment that one of the agents with less drug interactions be available.
Friendly amendment accepted.

Vote: Ayes: Unanimous (Dr. Heard was absent at this point of voting)

Motion carried.

IX. Expansion of CNS Stimulant Drug Class Review to include all ADHD Agents (Review scheduled for June)
The committee agreed to expand the June review to include ADHD drugs.

X. Review of Future Meeting Locations and Dates
Although the entire committee was planning to convene in Las Vegas for the June 17th meeting, only the small room in Las Vegas is available. Due to space constraints, teleconferencing may be necessary.

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XI. Public Comment-
Jim Morgan, Novartis, asked that the meeting site location be posted on the website, and that the state or FHSC make copies of public testimony handouts available at both sites.
Coleen Lawrence stated there will be videoconferencing for all meetings and therefore two sites will always be utilized for attendance and testimony.
Jeff Monaghan, FHSC, stated it is the responsibility of the presenter to have their information available for committee members and the public at both sites. This is stated in the Medicaid Operations Manual.

XII. Meeting adjourned at 4:45pm